UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THERESA E. BOYD-TAYLOR, MACHELL E. FOX, SHARON G. GOODENOUGH, MARK W. GRIMM, JUDY G. HALLFORD, JENNIFER A. HENSLEY, INMAN L. JONES, JR., KAY L. KOTAN, LEONARD R. LANZILLOTTI, THOMAS F. MOORE, MARGUERITE O'GARA, DONNIS L. PAYNE, KATHERINE D. REDMAN, ROCHELLE M. RIPPETOE, SALLY M. SANZONE, MELISSA A. SEABORN, DEANNA M. SMITH-BREZNY, JANET S. SOULSBY, JANETTE M. STOKES, CAROLYN E. UPTON, JULIANA WELLS-VARGAS, ROSEMARIE WILDER, AMIE J. WILLARD, BARBARA A. WILLIAMS, KELLY M. WORD, Plaintiffs, v. INDEVUS PHARMACEUTICALS, INC., F/K/A INTERNEURON PHARMACEUTICALS, INC.; WYETH, INC., F/K/A AMERICAN HOME PRODUCTS CORPORATION; WYETH PHARMACEUTICALS, INC F/K/A WYETH-AYERST PHARMACEUTICALS, INC., A DIVISION OF AMERICAN HOME PRODUCTS CORPORATION; AND BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Civil Action No. 04-11325-GAO **JURY TRIAL DEMANDED**

ANSWER, AFFIRMATIVE DEFENSES AND JURY DEMAND OF INDEVUS PHARMACEUTICALS, INC.

Defendant, Indevus Pharmaceuticals, Inc. ("IPI"), by its attorneys, and for its Answer to the Complaint, states as follows:

INTRODUCTION

1. In response to paragraph 1 of the Complaint, IPI specifically denies that Redux™ was defective or dangerous and denies that its copromotion with Wyeth-Ayerst Laboratories ("WALD") of Redux caused any injuries to Plaintiffs. IPI admits that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA"), that it marketed Redux in certain states at certain times following FDA approval of Redux, that Redux was also marketed by WALD, and that Redux was encapsulated by Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") pursuant to a "Contract Manufacturing Agreement" with IPI. IPI is without knowledge or information sufficient to form a belief as to the truth of the Plaintiffs' allegations of injury, except IPI denies that their injuries were caused by Redux. IPI is without knowledge sufficient to admit or deny Plaintiffs' allegations with respect to Pondimin®, except denies that it had any responsibility for Pondimin. All other allegations of paragraph 1 are denied.

PARTIES

2. IPI denies that Redux caused any injuries to Plaintiffs. IPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2 of the Complaint.

3. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint.

4. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint.

5. IPI denies the allegations of paragraph 5 of the Complaint.

6. IPI denies the allegations of paragraph 6 of the Complaint.

7. IPI denies the allegations of paragraph 7 of the Complaint.

8. IPI denies the allegations of paragraph 8 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 to the extent they relate to other defendants.

9. IPI denies the allegations of paragraph 9 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 to the extent they relate to defendants.

10. IPI denies the allegations of paragraph 10 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 to the extent they relate to other defendants. To the extent that the allegations of paragraph 10 constitute conclusions of law, no response is required.

11. IPI denies the allegations of paragraph 11 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 to the extent they relate to other defendants.

DEFENDANTS

12. IPI is without knowledge or information sufficient to form a belief as to the truth of the Plaintiff's allegations regarding contact between IPI representatives and Plaintiffs' physicians. IPI denies the remaining allegations of paragraph 12 of the Complaint, except it admits only that its principal place of business is 99 Hayden Avenue, One Ledgemont Center, Lexington, Middlesex County, Massachusetts; that IPI is incorporated under the laws of Delaware; that it submitted research regarding the safety and efficacy of Redux to the FDA in support of an NDA and marketed Redux to physicians in certain states at certain times following FDA approval of Redux; that IPI entered into a Patent and Know-How Sublicense and Supply Agreement with American Cyanamid Company on or about November 19, 1992; that IPI entered into a Contract Manufacturing Agreement with Boehringer on or about November 21, 1995; that IPI entered into a Copromotion Agreement with WALD on or about June 1, 1996; and that WALD also marketed Redux to physicians pursuant to the Copromotion Agreement. The Patent

and Know-How Sublicense and Supply Agreement, Contract Manufacturing Agreement, and Copromotion Agreement speak for themselves and attempts by Plaintiffs to characterize them are denied.

13. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint; except it admits only that IPI entered into a Patent and Know-How Sublicense and Supply Agreement with American Cyanamid Company on or about November 19, 1992, which agreement speaks for itself; that IPI entered into a Copromotion Agreement with WALD on or about June 1, 1996, which agreement speaks for itself; that WALD also marketed Redux pursuant to the Copromotion Agreement and denies Plaintiffs' attempts to characterize the agreements between IPI and American Cyanamid Company or WALD.

14. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the Complaint; except it admits only that IPI entered into a Patent and Know-How Sublicense and Supply Agreement with American Cyanamid Company on or about November 19, 1992, which agreement speaks for itself; that IPI entered into a Copromotion Agreement with WALD on or about June 1, 1996, which agreement speaks for itself; that WALD also marketed Redux pursuant to the Copromotion Agreement and denies Plaintiffs' attempts to characterize the agreements between IPI and American Cyanamid Company or WALD.

15. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15 of the Complaint; except it admits only that IPI entered into a "Contract Manufacturing Agreement" with Boehringer about November 21, 1995, which agreement speaks for itself and attempts by Plaintiff to characterize them are denied.

FACTUAL ALLEGATIONS

16. IPI denies the allegations of paragraph 16 of the Complaint.

17. IPI denies the allegations of paragraph 17 of the Complaint, except it admits only that dexfenfluramine is the right-sided isomer of fenfluramine and has certain serotonergic properties.

18. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18 of the Complaint.

19. IPI is without knowledge sufficient to form a belief as to the truth of the allegations of paragraph 19 of the Complaint, except it admits only that Aminorex was introduced to the European market in the 1960s.

20. IPI denies the allegations of paragraph 20 of the Complaint, except it admits only that certain studies suggested an association between Aminorex and pulmonary hypertension and that Aminorex was removed from the European market.

21. IPI is without knowledge sufficient to form a belief as to the truth of the allegations of paragraph 21 of the Complaint, except it admits only that Dr. Richard Wurtman was one of its founders and denies that fenfluramine and Aminorex are comparable drugs.

22. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Complaint.

23. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint. The studies referenced in paragraph 23 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

24. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Complaint, except it admits only that, on January 5, 1982, a patent for the use of dexfenfluramine for modifying feeding behavior was issued to Richard J. Wurtman and Judith J. Wurtman as inventors, and assigned to the Massachusetts Institute of Technology ("MIT") and that Les Laboratoires Servier ("Servier") had the right to grant sublicenses under such patent pursuant to a License Agreement with MIT.

25. IPI admits than case reports entitled "Pulmonary hypertension and fenfluramine" and "Irreversible pulmonary hypertension after treatment with fenfluramine" appeared in the *British Medical Journal* in, respectively, October 1981 and January 1986. Said reports for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. IPI denies the remaining allegations of paragraph 25.

26. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26 of the Complaint.

27. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27 of the Complaint, except it admits only that Servier sold dexfenfluramine as Adifax in England and Isomeride in France during the 1980s.

28. IPI denies the allegations of paragraph 28 of the Complaint, except it admits only that Dr. Wurtman did some research and testing regarding dexfenfluramine.

29. IPI admits that it entered into a Patent and Know-How License Agreement with Servier as of February 7, 1990, pursuant to which Servier granted IPI the right to manufacture, use and sell dexfenfluramine in the United States. Said Patent and Know-How License Agreement speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

30. IPI denies the allegations of paragraph 30 of the Complaint.

31. IPI admits that Biologie Servier completed a carcinogenicity study of repeated oral administration of dexfenfluramine to Fischer 344 rats on September 19, 1990, which was submitted to the FDA as part of the Redux NDA. Said study speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI admits that, by the time the study was submitted to the FDA, it was aware that Biologie Servier's carcinogenicity study of repeated oral administration of dexfenfluramine to Fischer 344 rats had found no evidence of carcinogenicity. To the extent Plaintiffs suggest that there were any other conclusions to be

drawn from the study, the allegations are denied as are all other allegations of paragraph 31 of the Complaint not expressly admitted.

32. IPI denies the allegations of paragraph 32 of the Complaint, except it admits only that it filed a petition to deschedule fenfluramine with the DEA on or about March 18, 1991. Said petition speaks for itself and any attempts to characterize it are improper and are denied.

33. IPI admits the allegations of paragraph 33 of the Complaint.

34. IPI denies the allegations of paragraph 34 of the Complaint to the extent they relate to IPI. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34 to the extent they relate to other defendants, except IPI responds that Dr. Weintraub's articles speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

35. IPI denies the allegations of paragraph 35 of the Complaint, except it admits only that IPI entered into a Patent and Know-How Sublicense and Supply Agreement with American Cyanamid Company on or about November 19, 1992, and that American Home Products Corp. (now known as Wyeth) succeeded to American Cyanamid Company's interests under such agreement. The agreement speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

36. IPI admits only that, on April 15, 1993, Dr. Bobby Sandage, together with representatives of Cyanamid/Lederle and others, attended a meeting with Dr. Stuart Rich, of the Section of Cardiology at the University of Illinois, a Principal Investigator and member of the Steering Committee for the NIH Registry for the Characterization of PPH and that a possible association between primary pulmonary hypertension ("PPH") and dexfenfluramine was discussed at that meeting. The meeting was over ten years ago and IPI has insufficient knowledge or information at this time to admit or deny Plaintiffs' allegations regarding what was said at such meeting and, therefore, denies the remaining allegations of paragraph 36 of the

Complaint. IPI denies the remaining allegations of paragraph 36 of the Complaint to the extent that they relate to IPI.

37. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37 of the Complaint; except IPI responds that Dr. Brenot's article speaks for itself and any attempts by Plaintiffs to characterize it are improper and denied.

38. IPI denies that allegations of paragraph 38 of the Complaint to the extent that they relate to IPI or Redux, except it admits only that it submitted the Redux NDA to the FDA on May 23, 1993; that the NDA was officially filed on July 24, 1993; and that it submitted the Noble Study, the Van Italie Study and the Index Study for the FDA's consideration as part of the Redux NDA. These documents speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

39. IPI denies the allegations of paragraph 39 of the Complaint, including subparts, except it admits only that Bruce Sturgeon audited the Noble and Index studies. Mr. Sturgeon's reports speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

40. IPI denies the allegations of paragraph 40 of the Complaint.

41. IPI denies the allegations of paragraph 41 of the Complaint and further states that the articles referenced therein speak for themselves and any attempts by Plaintiff to characterize them are improper and denied.

42. IPI denies the allegations of paragraph 42 of the Complaint.

43. IPI denies the allegations of paragraph 43 of the Complaint, except it admits only that it was aware of preliminary reports of the International Primary Pulmonary Hypertenstion Study ("IPPHS"), that it provided such data to the FDA and included a PPH warning based on such reports in the FDA-approved Redux label. IPI further states that the report referenced in paragraph 43 speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

44. IPI denies the allegations of paragraph 44 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 44 of the Complaint to the extent they relate to other defendants.

45. IPI denies the allegations of paragraph 45 of the Complaint, except it admits only that Dr. Sandage spoke with Lisa Stockbridge of the FDA on or about March 23, 1994, to discuss the status of the Redux NDA.

46. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46 of the Complaint.

47. IPI is without knowledge sufficient to admit or deny the allegations of paragraph 47 of the Complaint, except it admits only that American Home Products Corp. (now Wyeth) eventually succeeded American Cyanamid Company under the Patent and Know-How Sublicense and Supply Agreement with IPI.

48. IPI denies the allegations of paragraph 48 of the Complaint.

49. IPI denies the allegations of paragraph 49 of the Complaint.

50. IPI denies the allegations of paragraph 50 of the Complaint.

51. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51 of the Complaint.

52. In response to paragraph 52 of the Complaint, IPI admits that it received a "not approvable" letter from the FDA (signed by James Bilstad, M.D.) dated February 17, 1995. Said letter speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

53. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 53 of the Complaint.

54. To the extent paragraph 54 of the Complaint refers to a document, such document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 54.

55. IPI states that the documents referenced in paragraph 55 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. IPI denies the remaining allegations of paragraph 55.

56. IPI states that the documents and testimony referenced in paragraph 56 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. IPI denies the remaining allegations of paragraph 56.

57. IPI denies the allegations of paragraph 57 of the Complaint, except it admits only that Alexander Haig was formerly a member of IPI's Board of Directors.

58. IPI denies the allegations of paragraph 58 of the Complaint.

59. To the extent paragraph 59 of the Complaint refers to a letter dated October 2, 1995, by Dr. Rich, such document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. The remaining allegations of paragraph 59 are denied.

60. IPI denies the allegations of paragraph 60 of the Complaint, except it admits only that its representative spoke with Dr. Leo Lutwak on October 12, 1995, to discuss labeling issues.

61. IPI denies the allegations of paragraph 61 of the Complaint.

62. IPI denies the allegations of paragraph 62 of the Complaint.

63. IPI admits that it entered into a Contract Manufacturing Agreement with Boehringer on November 21, 1995. Said document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

64. IPI admits that, by letter dated January 18, 1996, the FDA advised IPI of certain requested changes to the Redux label. This document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. The remaining allegations of paragraph 64 of the Complaint are denied.

65. IPI admits the allegations of paragraph 65 of the Complaint.

66. IPI denies the allegations of paragraph 66 of the Complaint, except it admits only that IPI employee Sonja Loar spoke with Randy Hedin of the FDA on July 17, 1996, regarding a meeting with the FDA to discuss Redux labeling and that the alternatives of a black box or bold face/all capitalization in connection with the PPH warning on the Redux label were mentioned as items for discussion at such meeting.

67. IPI denies the allegations of paragraph 67 of the Complaint, except it admits only that representatives of IPI met with the FDA on August 19, 1996.

68. In response to paragraph 68 of the Complaint, IPI admits that information regarding the results of the IPPHS was publicly available on or about August 26, 1996, and that IPI submitted revised labeling to the FDA to reflect such data. The study speaks for itself and any attempts by Plaintiffs to characterize it are improper and denied.

69. In response to paragraph 69 of the Complaint, IPI admits that an article appeared in the *New England Journal of Medicine* dated August 29, 1996, entitled "Appetite-suppressant drugs and the risk of primary pulmonary hypertension," that Dr. Stuart Rich was one of the authors of the article and that the article reported the results of the IPPHS. The article speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 69 of the Complaint.

70. IPI denies the allegations of paragraph 70 of the Complaint to the extent they relate to IPI or Redux, except it admits only that it was aware of preliminary reports of the IPPHS, that it provided such data to the FDA and included a PPH warning based on such reports in the FDA-approved label. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70 to the extent they relate to other defendants.

71. IPI denies the allegations of paragraph 71 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 71 to the extent they relate to other defendants.

72. IPI denies the allegations of paragraph 72 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 72 to the extent they relate to other defendants.

73. IPI denies the allegations of paragraph 73 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 73 to the extent they relate to other defendants.

74. IPI admits that it had available to it information concerning the safety and efficacy of dexfenfluramine, which information was submitted to the FDA as part of the Redux NDA, but otherwise denies the allegations of paragraph 74 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 74 to the extent they relate to other defendants.

75. To the extent paragraph 75 of the Complaint refers to a letter dated April 9, 1996, by Dr. B. Taylor Thompson, such document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 75.

76. IPI denies the allegations of paragraph 76 of the Complaint; except it admits only that on or about April 29, 1996, the FDA approved Redux for sale in the United States.

77. IPI denies the allegations of paragraph 77 of the Complaint; except that it admits only that that IPI entered into a Copromotion Agreement with WALD on or about June 1, 1996, pursuant to which IPI and WALD jointly promoted Redux to licensed health care providers. The Copromotion Agreement speaks for itself and any attempts by Plaintiff to characterize it are improper and are denied.

78. IPI denies the allegations of paragraph 78 of the Complaint.

79. IPI denies the allegations of paragraph 79 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 79 to the extent they relate to other defendants.

80. IPI denies the allegations of paragraph 80 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 80 to the extent they relate to other defendants.

81. IPI admits that on or about July 8, 1997, the Mayo Clinic issued a press release discussing diet medications. Said press release speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 81.

82. The documents referenced in paragraph 82 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. IPI denies the remaining allegations of paragraph 82.

83. IPI denies the allegations of paragraph 83 of the Complaint to the extent they relate to IPI or Redux; except it admits only that Redux was voluntarily withdrawn from the market on or about September 15, 1997. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 83 to the extent they relate to other defendants.

84. IPI admits that the FDA issued a Public Health Advisory on July 8, 1997. The Public Health Advisory speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 84 of the Complaint.

85. IPI admits that it voluntarily withdrew Redux from the market on September 15, 1997. The report referenced in paragraph 85 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 85 to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 85 to the extent they relate to other defendants.

86. The report referenced in paragraph 86 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 86.

87. The report referenced in paragraph 87 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. IPI denies the remaining allegations of paragraph 87.

88. In response to paragraph 88 of the Complaint, IPI admits that a report appeared in Morbidity and Mortality Weekly Report dated November 14, 1997, that included recommendations for persons exposed to fenfluramine or dexfenfluramine, developed by the FDA, the National Institutes of Health and the Centers for Disease Control. Said report speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

GENERAL ALLEGATIONS

89. IPI denies the allegations of paragraph 89 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 89 to the extent they relate to other defendants.

90. IPI denies the allegations of paragraph 90 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 90 to the extent they relate to other defendants.

91. IPI denies the allegations of paragraph 91 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 91 to the extent they relate to other defendants.

92. IPI denies the allegations of paragraph 92 of the Complaint.

93. IPI denies the allegations of paragraph 93 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 93 to the extent they relate to other defendants.

94. IPI denies the allegations of paragraph 94 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 94 to the extent they relate to other defendants.

95. IPI denies the allegations of paragraph 95 of the Complaint.

96. IPI denies the allegations of paragraph 96 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96 to the extent they relate to other defendants.

97. IPI denies the allegations of paragraph 97 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 97 to the extent they relate to other defendants.

98. IPI denies the allegations of paragraph 98 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 98 to the extent they relate to other defendants.

99. IPI denies the allegations of paragraph 99 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 99 to the extent they relate to other defendants.

100. IPI denies the allegations of paragraph 100 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 100 to the extent they relate to other defendants.

101. IPI denies the allegations of paragraph 101 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 101 to the extent they relate to other defendants.

102. IPI denies the allegations of paragraph 102 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 102 to the extent they relate to other defendants.

103. IPI denies the allegations of paragraph 103 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 103 to the extent they relate to other defendants.

104. IPI denies the allegations of paragraph 104 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 104 to the extent they relate to other defendants.

105. IPI denies the allegations of paragraph 105 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 105 to the extent they relate to other defendants.

106. IPI denies the allegations of paragraph 106 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 106 to the extent they relate to other defendants.

107. IPI denies the allegations of paragraph 107 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 107 to the extent they relate to other defendants.

108. In response to paragraph 108, IPI admits only to those duties imposed by law. To the extent that the allegations of paragraph 108 of the Complaint constitute conclusions of law, no response is required.

109. IPI denies the allegations of paragraph 109 of the Complaint to the extent they relate to IPI or Redux; except it admits only that it provided to physicians accurate and FDA-approved information regarding the benefits and risks of Redux based upon available medical information at the relevant times. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 109 to the extent they relate to other defendants.

110. IPI denies the allegations of paragraph 110 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 110 to the extent they relate to other defendants.

111. IPI denies the allegations of paragraph 111 of the Complaint.

112. IPI denies the allegations of paragraph 112 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 112 to the extent they relate to other defendants.

113. IPI denies the allegations of paragraph 113 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 113 to the extent they relate to other defendants.

114. IPI admits that Redux was intended to reach users without a substantial change in the condition in which they were sold. IPI is without knowledge or information sufficient to form a belief as to whether the subject pharmaceuticals actually reached prescribing physicians or consumers, including Plaintiffs, without a substantial change in the condition in which they were sold. IPI therefore denies this allegation and denies the remaining allegations of paragraph 114 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 114 to the extent they relate to other defendants.

115. IPI denies the allegations of paragraph 115 of the Complaint.

116. IPI denies the allegations of paragraph 116 to the extent they relate to IPI or Redux, except that it admits only that IPI did at certain times market and copromote with WALD/Redux in certain states. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 116 to the extent they relate to other defendants. To the extent that the allegations of paragraph 116 constitute conclusions of law, no response is required.

117. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 117 of the Complaint.

COUNT I
STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN

118. In response to paragraph 118 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

119. IPI denies the allegations of paragraph 119 of the Complaint to the extent they relate to IPI or Redux, except it admits only that it submitted research regarding the safety and efficacy of Redux to the FDA in support of an NDA and that it marketed Redux in certain states at certain times following FDA approval of Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 119 to the extent they relate to other defendants.

120. IPI admits that it submitted research regarding the safety and efficacy of Redux to the FDA in support of an NDA, that it marketed Redux in certain states at certain times following FDA approval of Redux, that Redux was intended to reach users without a substantial change in the condition in which they were sold. IPI is without knowledge or information sufficient to form a belief as to whether the subject pharmaceuticals actually reached prescribing physicians or consumers, including Plaintiffs, without a substantial change in the condition in which they were sold. IPI therefore denies this allegation and denies the remaining allegations of paragraph 120 of the Complaint. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 120 to the extent they relate to other defendants.

121. IPI denies the allegations of paragraph 121 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 121 to the extent they relate to other defendants.

122. IPI denies the allegations of paragraph 122 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 122 to the extent they relate to other defendants.

123. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 123 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies that Redux was in a defective condition and otherwise denies the allegations of paragraph 123.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

COUNT II
STRICT PRODUCT LIABILITY – FAILURE TO WARN

124. In response to paragraph 124 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

125. IPI denies the allegations of paragraph 125 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 125 to the extent they relate to other defendants.

126. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 126 of the Complaint.

127. IPI denies the allegation of paragraph 127 of the Complaint that Redux was defective. IPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 127.

128. The allegation of paragraph 128 of the Complaint constitutes a conclusion of law, to which no response is required.

129. IPI denies the allegations of paragraph 129 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 129 to the extent they relate to other defendants.

130. IPI denies the allegations of paragraph 130 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 130 to the extent they relate to other defendants.

131. IPI denies the allegations of paragraph 131 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 131 to the extent they relate to other defendants.

132. IPI denies the allegations of paragraph 132 of the Complaint, except it admits only to any duties imposed by law. To the extent the allegations of paragraph 132 constitute conclusions of law, no response is required.

133. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 133 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to the Redux, denies Plaintiffs' failure to warn allegations and otherwise denies the allegations of paragraph 133 to the extent that they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 133 to the extent they relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

COUNT III
NEGLIGENCE

134. In response to paragraph 134 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

135. IPI denies the allegations of paragraph 135 of the Complaint to the extent they relate to IPI or Redux, except IPI admits only that it submitted research regarding the safety and efficacy of Redux to the FDA in support of an NDA and that it marketed Redux, in certain states, at certain times following FDA approval of Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 135 to the extent they relate to other defendants.

136. IPI denies the allegations of paragraph 136 of the Complaint, except it admits only to any duties imposed by law. To the extent the allegations of paragraph 136 constitute conclusions of law, no response is required.

137. IPI denies the allegations of paragraph 137 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 137 to the extent they relate to other defendants.

138. IPI denies the allegations of paragraph 138 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 138 to the extent they relate to other defendants.

139. IPI denies the allegations of paragraph 139 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 139 to the extent they relate to other defendants.

140. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 140 of the Complaint purporting to describe Plaintiffs' injuries, but denies Plaintiffs' negligence allegations and otherwise denies the allegations of paragraph 140 to the extent that they may relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 140 to the extent that they may relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

COUNT IV
FRAUDULENT/NEGLIGENT MISREPRESENTATION

141. In response to paragraph 141 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

142. IPI denies the allegations of paragraph 142 of the Complaint, except it admits only to any duties imposed by law. To the extent the allegations of paragraph 142 constitute conclusions of law, no response is required.

143. IPI denies the allegations of paragraph 143 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 143 to the extent they relate to other defendants.

144. IPI denies the allegations of paragraph 144 of the Complaint to the extent they relate to IPI or Redux; except IPI admits only that it provided to physicians accurate and FDA-approved information regarding the benefits and risks of Redux based upon available medical information at the relevant times. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 144 to the extent they relate to other defendants.

145. IPI denies the allegations of paragraph 145 of the Complaint.

146. IPI denies the allegations of paragraph 146 of the Complaint, including subparts, to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 146 to the extent they relate to other defendants.

147. IPI denies the allegations of paragraph 147 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 147 to the extent they relate to other defendants.

148. IPI denies the allegations of paragraph 148 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 148 to the extent they relate to other defendants.

149. IPI denies the allegations of paragraph 149 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 149 to the extent they relate to other defendants.

150. IPI denies the allegations of paragraph 150 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 150 to the extent they relate to other defendants.

151. IPI denies the allegations of paragraph 150 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 150 to the extent they relate to other defendants.

152. IPI denies the allegations of paragraph 152 of the Complaint, except IPI admits only to any duties imposed by law. To the extent the allegations of paragraph 152 constitute conclusions of law, no response is required.

153. IPI denies the allegations of paragraph 153 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 153 to the extent they relate to other defendants. To the extent the allegations of paragraph 153 constitute conclusions of law, no response is required.

154. IPI denies the allegations of paragraph 154 of the Complaint to the extent they relate to IPI or Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 154 to the extent they relate to other defendants.

155. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 155 of the Complaint, to the extent they relate to IPI or Redux, purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' misrepresentation and fraudulent concealment allegations and otherwise denies the allegations of paragraph 155. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 155 to the extent they relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

COUNT V
FRAUDULENT CONCEALMENT
(AGAINST DEFENDANT IPI ONLY)

156. In response to paragraph 156 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

157. To the extent paragraph 157 refers to IPI's 2002 Annual Report, said report speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied, as are all other allegations of paragraph 157 of the Complaint.

158. IPI denies the allegations of paragraph 158 of the Complaint, except it admits only that it has denied and does deny that it concealed known risks regarding Redux and has, in appropriate cases, denied a causal relationship between Redux use and injury.

159. IPI denies the allegations of paragraph 159 of the Complaint, except IPI admits only to any duties imposed by law. To the extent the allegations of paragraph 159 constitute conclusions of law, no response is required.

160. IPI denies the allegations of paragraph 160 of the Complaint.

161. IPI denies the allegations of paragraph 161 of the Complaint.

162. IPI denies the allegations of paragraph 162 of the Complaint.

163. IPI denies the allegations of paragraph 163 of the Complaint.

164. IPI denies the allegations of paragraph 164 of the Complaint.

165. IPI denies the allegations of paragraph 165 of the Complaint.

166. IPI denies the allegations of paragraph 166 of the Complaint.

167. IPI denies the allegations of paragraph 167 of the Complaint, except IPI admits only to any duties imposed by law. To the extent the allegations of paragraph 167 constitute conclusions of law, no response is required.

168. IPI denies the allegations of paragraph 168 of the Complaint. To the extent the allegations of paragraph 168 constitute conclusions of law, no response is required.

169. IPI denies the allegations of paragraph 169 of the Complaint.

170. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 170 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' misrepresentation and fraudulent concealment allegations and otherwise denies the allegations of paragraph 170.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

COUNT VI
G.L. c. 93A UNFAIR AND DECEPTIVE PRACTICES
(AGAINST DEFENDANTS IPI AND BOEHRINGER ONLY)

171. In response to paragraph 171 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

172. IPI admits that its principal place of business is located in Massachusetts and that it marketed Redux to physicians in certain states, including Massachusetts, at certain times following FDA approval of Redux. To the extent that the allegations of paragraph 172 constitute conclusions of law, no response is required.

173. IPI denies the allegations of paragraph 173 of the Complaint, except it admits only that it marketed Redux to physicians in certain states at certain times following FDA approval of Redux. To the extent that the allegations of paragraph 173 constitute conclusions of law, no response is required.

174. IPI denies the allegations of paragraph 174 of the Complaint.

175. IPI denies the allegations of paragraph 175 of the Complaint.

176. IPI denies the allegations of paragraph 176 of the Complaint.

177. IPI denies the allegations of paragraph 177 of the Complaint.

178. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what Plaintiffs relied upon in paragraph 178 of the Complaint and denies the remaining allegations of paragraph 178.

179. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 179 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' allegations of unfair and deceptive acts or practices and otherwise denies the allegations of paragraph 179.

180. IPI denies the allegations of paragraph 180 of the Complaint.

181. IPI denies the allegations of paragraph 181 of the Complaint.

182. IPI denies the allegations of paragraph 182 of the Complaint.

183. IPI denies the allegations of paragraph 183 of the Complaint.

184. IPI denies the allegations of paragraph 184 of the Complaint.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

GENERAL DENIAL

IPI denies each and every allegation of the Complaint that is not specifically admitted to be true.

AFFIRMATIVE DEFENSES

FIRST. The Complaint and each claim contained therein fail to state a claim upon which relief can be granted.

SECOND. IPI's product in all respects met or exceeded standards of the industry at the time of its manufacture, sale, and distribution.

THIRD. Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

FOURTH. IPI's product was not dangerous when used in a reasonable and foreseeable manner and for its intended purpose.

FIFTH. If Plaintiffs have sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were in no way caused by IPI and for which IPI is not liable.

SIXTH. Plaintiffs may not recover from IPI because the methods, standards, or techniques of designing, manufacturing, and labeling of IPI's product complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, and labeled. The state-of-the-art was and is such that there was and is no generally accepted or recognized knowledge of any defective quality of the product at issue, giving rise to no duty by IPI to warn of such allegedly defective quality.

SEVENTH. Plaintiffs' claims, if any, are barred, in whole or in part, by the applicable statutes of limitations and of repose.

EIGHTH. Plaintiffs' claims, if any, are barred, in whole or in part, by the doctrines of laches, waiver, unclean hands, estoppel and/or ratification.

NINTH. Plaintiffs' claims pursuant to G.L. c. 93A, if any, are barred by Plaintiffs' failure to give proper or timely notice.

TENTH. To the extent Plaintiffs' claims relate to IPI's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States and by applicable State Constitutions, such claims are barred.

ELEVENTH. Plaintiffs' claims are barred, in whole or in part, by their failure to mitigate any damages allegedly sustained.

TWELFTH. Plaintiffs' claims are preempted, in whole or in part, by federal laws and regulations, including (without limitation) those governing the labeling, advertisement and sale of pharmaceutical products.

THIRTEENTH. Plaintiffs' claims are barred or reduced by their contributory and/or comparative negligence, and/or contributory and/or comparative fault.

FOURTEENTH. Plaintiffs' damages, if any, were the direct result of their pre-existing medical conditions, and/or occurred by operation of nature or as a result of circumstances over which IPI had and continues to have no control.

FIFTEENTH. Plaintiffs' injuries, if any, were not foreseeable.

SIXTEENTH. Plaintiffs' claims are barred by Plaintiffs' assumption of risk and consent.

SEVENTEENTH. IPI is not subject to liability under *Restatement (Second) of Torts* § 402A, comment k.

EIGHTEENTH. IPI is not subject to liability under *Restatement (Third) of Torts: Products Liability*, § 6.

NINETEENTH. Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have already indemnified or will in the future, with reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

TWENTIETH. The benefits of the product at issue outweigh the risks, if any, alleged in Plaintiffs' Complaint.

TWENTY-FIRST. Plaintiffs' claims are barred by the intervention of a learned intermediary whose omissions, acts, or faults are the cause of Plaintiffs' damages, if any.

TWENTY-SECOND. Plaintiffs' claims are barred because of Plaintiffs' failure to join necessary and indispensable parties.

TWENTY-THIRD. Plaintiffs' claims are barred by their alteration, modification, abuse, and/or misuse of the product at issue.

TWENTY-FOURTH. IPI had no duty to warn the Plaintiffs.

TWENTY-FIFTH. IPI's product was not unreasonably dangerous.

TWENTY-SIXTH. IPI had no actual or constructive knowledge of the dangers of the product as alleged in the Complaint.

TWENTY-SEVENTH. No action or inaction by IPI was the proximate cause of Plaintiffs' injuries, if any.

TWENTY-EIGHTH. IPI's product contained no defect that was the cause of Plaintiffs' injuries, if any.

TWENTY-NINTH. The warnings given by IPI were adequate.

THIRTIETH. Plaintiffs have failed to allege fraud with sufficient particularity.

THIRTY-FIRST. Plaintiffs' injuries, if any, were caused by their own failure to read or to heed the warnings given, or to follow IPI's recommendations regarding the use of the product.

THIRTY-SECOND. IPI's product was properly prepared and accompanied by proper directions and warnings.

THIRTY-THIRD. Plaintiffs did not exercise reasonable care as required by the circumstances.

THIRTY-FOURTH. At the time Plaintiffs used IPI's product, their use was unanticipated, unforeseeable, and unintended.

THIRTY-FIFTH. Adequate warnings were given to informed intermediaries.

THIRTY-SIXTH. This court is not the proper venue for Plaintiffs' claims.

THIRTY-SEVENTH. IPI acted reasonably and in good faith at all times.

THIRTY-EIGHTH. Plaintiffs' claims are barred by the doctrine of avoidable consequences.

THIRTY-NINTH. IPI denies any and all culpability and liability, but if IPI is ultimately found to be liable, then the liability of IPI, if any, to the Plaintiffs for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom Plaintiffs could have obtained personal jurisdiction with due diligence.

FORTIETH. The Complaint fails to allege a claim for which punitive or exemplary damages can be recovered.

FORTY-FIRST. Plaintiffs' claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines

clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution and applicable provisions of the relevant state constitutions.

DEFENSES RESERVED

IPI hereby gives notice that it intends to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter and hereby reserves its right to amend its Answer and to assert any such defense.

DEMAND FOR BIFURCATED TRIAL

If Plaintiffs are allowed to proceed to trial upon any claims for punitive or exemplary or exemplary damages, such claims, if any, must be bifurcated from the other issues.

DEMAND FOR JURY TRIAL

IPI demands a jury trial as to all issues so triable in this action.

WHEREFORE, Defendant IPI respectfully requests that this Court:

(a) Grant IPI judgment on all of Plaintiffs' claims and dismiss the Complaint with prejudice;

(b) Award IPI its costs and attorneys' fees for defense of the Complaint;

(c) Award IPI such other relief as the Court deems just and proper.

Dated: August 2, 2004
Boston, Massachusetts

Respectfully submitted,

/s/Matthew J. Matule
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